

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herein.

The Office Action of October 3, 2003 required restriction to one of the following Groups under 35 U.S.C. §121:

- Group I: Claims 2, 5, 7, 9, drawn to a polypeptide monomer comprising T4 Gp31 with heterologous amino acid(s) inserted, classified in class 530, subclass 300;
- Group II: Claims 2, 6, 8, 10, drawn to a polypeptide monomer comprising *E. coli* Gro ES with heterologous amino acid(s) inserted, classified in class 530, subclass 300;
- Group III: Claims 2, 11, drawn to a polypeptide comprising a scaffold with a heterologous sequence at the C or N terminal positions, classified in class 530, subclass 300;
- Group IV: Claims 22, 28, drawn to use of a polypeptide for detection, classified in class 435, subclass 4;
- Group V: Claims 22, 28, drawn to use of a polypeptide for detection, classified in class 424, subclass 184.1;
- Group VI: Claims 35, 36, drawn to a nucleic acid sequence, classified in class 536, subclass 23.4.

Applicants elect, with traverse, the claims of Group II, i.e. claims 2, 6, 8, and 10, drawn to a polypeptide monomer comprising *E. coli* Gro ES with heterologous amino acid(s) inserted.

Additionally, the Office Action required the election of a single species for prosecution. The Office Action did not specify what type of species was to be elected. Applicants have assumed that the species in question was to be elected from one of the oligomerisable protein scaffolds set forth in claim 2, and accordingly select *E. coli* GroES, with traverse. Should Applicants be mistaken as to the election required, it is respectfully requested that the Office Action be withdrawn and a new Office Action issued which explicitly sets forth the species to be included in the election.

The MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

It is respectfully submitted that the assertions made in the Office Action that the claims of Groups I to VI are distinct or unrelated, are without foundation.

The claims of Group I are drawn to polypeptide monomers comprising bacteriophage T4 Gp31 with heterologous amino acid(s) inserted. The claims of Group II are drawn to polypeptide monomers comprising *E. coli* Gro ES with heterologous amino acid(s) inserted. As stated in the specification at page 3, line 32 to page 4, line 1, both bacteriophage T4 Gp31 and *E. coli* Gro ES are chaperonin 10 (cpn10) proteins. Furthermore, it is stated on page 4 line 26 that cpn10 proteins possess a “mobile loop” within their structure. The claims of Group III are drawn to polypeptide monomers with heterologous amino acid(s) inserted at the C or N terminal positions. As the claims of Groups I and II are directed to polypeptide monomers with heterologous amino acid(s) inserted without reference to specific insertion locations, the polypeptide monomers of Group III necessarily comprise a subset of the polypeptide monomers of Groups I and II. Thus, in performing a search and examination of the polypeptide monomers of Groups I and II, the Examiner will also have performed a search and examination of the polypeptide monomers of Group III, whether intentionally or not.

Thus, the polypeptide monomers of Groups I, II, and III are clearly related. Furthermore, any search and examination of the claims of Groups I, II and III will likely be co-extensive and, in any event, will involve such inter-related art that the search and examination of Groups I to III can be made without undue burden on the Examiner.

In addition, any search and examination of the subject matter of Groups IV, V, and VI will likely be co-extensive with the search and Examination of the subject matter of Groups I, II, and III. Groups IV and V relate to uses of the polypeptides of Groups I, II and III. Any search and examination relating to the use of these polypeptides will necessitate a search of the same art, and an examination of the same issues, as would be necessitated by performing a search and examination of the polypeptides themselves. Likewise, a search and examination of Group VI, drawn to nucleic acid sequences, will likely be co-extensive with a search and examination of all previous Groups, as the nucleotides of Group VI encode the polypeptides of all previous Groups. If the present restriction requirement is upheld, the Examiner will have to review the same co-extensive art on multiple occasions, resulting in inefficiencies and unnecessary expenditures by both the Applicants and the PTO.

It is again respectfully submitted that MPEP § 803 directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be

made without serious burden, ... even though it includes claims to distinct or independent inventions." *Id.* The Office Action provides no showing that search and examination of the entire application would be a serious burden. It is respectfully submitted that it would not be an undue burden to examine the claims of Group I to Group VI together.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Furthermore, the Examiner is respectfully requested to review M.P.E.P. §808.01(a), which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, the Office Action fails to state what species requires election. Applicants have assumed that the election of species is directed towards the oligomerisable protein scaffolds of claim 2, and the comments herein are accordingly directed to the oligomerisable protein scaffolds of claim 2.

It is respectfully submitted there is a disclosure of relationship between the claimed species. Claim 2 recites possible oligomerisable protein scaffolds into which heterologous amino acid sequences can be inserted, including bacteriophage T4 Gp31, *E. coli* GroES, and *E. coli* GroEL. On page 2 of the specification (paragraph beginning line 4) it is stated that GroEL (also known as cpn60) and GroES (also known as cpn10) are both *E. coli* chaperonin proteins. In addition, it is stated that GroES is actually a co-chaperone for GroEL, both proteins being present in the same protein complex. Furthermore, in the same paragraph it is described that both chaperonin proteins are widespread throughout all organisms. Thus, as stated on page 3 line 32 to page 4 line 2, the bacteriophage protein T4 Gp31 is a cpn10 family member, and a member of the the cpn60/cpn10 chaperonin system. Consequently, there is a disclosed relationship between the oligomerisable protein scaffolds of claim 2.

Furthermore, the Office Action has made no showing that searching the oligomerisable protein scaffolds of claim 2 would constitute an undue burden. Consequently, it is respectfully submitted that the requirement for an election of species is inappropriate.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction and election requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made, and it has not been shown that the claims of Groups I to VI constitute distinct inventions. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. Furthermore, the election requirement has not been shown to be proper, especially since, *inter alia*: 1) the requisite showing of serious burden has not been made in the Office Action; and, 2) there are relationships among the claimed species. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the Restriction Requirement, and early and favorable examination on the merits of all of the claimed subject matter, is earnestly solicited.

Respectfully submitted,

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